Confidential Final

FOCUS REPORT
New Chemicals Program

PART I: BACKGROUND

Written By: KMB

FOCUS DATE: 11/20/2007 **FOCUS CHAIR:** K. Moss

COMPANY: [redacted]

CASE NUMBER(S): L08-0037 **through** **and**

PART II: SAT RESULTS

HEALTH: 3 **ECOTOX:** 3 **OCCUPATIONAL EXPOSURE:** 1-2A **CONSUMER EXPOSURE:** 2 **ENVIRONMENTAL RELEASES:** 3

Additional SAT Information:

PART III: OTHER FACTORS

a. **PRODUCTION VOLUME:** [redacted]

b. **PROD VOL OTHER:** [redacted]

c. **USE:** [redacted]

d. **REGULATORY HISTORY:** [redacted]

e. **TEST DATA:**

f. [redacted]

g. **MSDS:** ☑

h. **CATEGORY:** **CATEGORY 2:**

8 0 0 8 0 0 0 0 5 5 2

PART IV: SUMMARY OF SAT ASSESSMENT

CASE NUMBER: L08-0037

[redacted]

FATE: [redacted]
solid with mp = sublimes at 204 C (M)
log Kow = 2.0 (EPI)
S = dispersible (P)
vp < 0.032 mm Hg or torr at 25 □C (P)
bp = sublimes at 204 C (M)
H < 1.0E-8 (P)
log Koc =3.1 (P)
log fish BCF = 0.50 (P)
sorption to sludge = moderate
submitted test data for aerobic biodegradation were:
[redacted]
POTW removal = 0%
time for complete ultimate aerobic biodegradation > months
sorption to soils and sediments = moderate
PBT Potential: P2B1T3

HEALTH: Absorption poor thru skin, good thru lungs, and moderate thru GI tract based on analogs;

submitted test data with this PMN were:
rat acute oral LD100 = 2.0 g/kg with systemic toxic signs, with NOEL = 300 mg/kg;

moderate skin irritation in rabbits;
severe eye irritation in rabbits;
Ames test was negative;
E. coli test was negative;
no skin sensitization in mice up to 50% ai (LLNA);

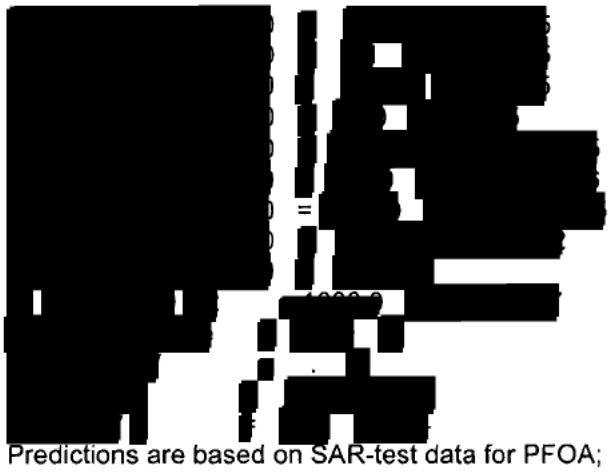
[redacted]

By analogy to PFOA, there is concern for reproductive and developmental effects, liver effects, immunotoxicity, and a marginal concern for oncogenicity. In the assessment conducted by the state of West Virginia with input from EPA, the RfD for oral exposure was determined to be 0.004 mg/kg/day and the RfC for inhalation exposure was determined to be 1 ug/m3. Some of the key findings for non-cancer assessment are for PFOA and/or its salts:
90-day dietary study in male rats - NOAEL = 0.47 mg/kg/day based on liver effects at 1.44 mg/kg/day. The benchmark dose was 1.3 mg/kg/day;
two-generation reproduction study in rats, gavage - LOAEL = 1 mg/kg/day based on increased liver and kidney weights in P and F1 generations;
2-year dietary study in rats - NOAEL = 1.3 mg/kg/day in males based on increased liver weight, hepatic cystoid degeneration, increased ALT enzyme activity, testicular vascular mineralization and LOAEL = 1.6 mg/kg/day in females based on an increase in the incidence of ovarian stromal tubular hyperplasia; the benchmark dose was 0.73 mg/kg/day based on liver effects in males;
26-week oral study in cynomolgus monkeys - LOAEL is from 3 to 10 mg/kg/day based on 30% increased absolute liver weight with no NOAEL;
2-week dermal study in rats - increased liver weight and liver pathology;
2-week inhalation study in male rats - liver effects at 7.6 mg/m3; severe toxicity including the death of one animal at 84 mg/m3, increased lung and testes weight at 84 mg/m3;
inhalation developmental toxicity study in rats - maternal deaths, reduced maternal weights, reduced fetal weights at 25 mg/m3;
oral developmental toxicity in rabbits - increase in skeletal variations at 50 mg/kg.

high concern for toxicity

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) FOR [redacted] are:

[redacted]



Predictions are based on SAR-test data for PFOA; SAR chemical class = PFOA; pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness < 150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;
moderate concern for aquatic toxicity;
high concern for reproductive toxicity to birds and wild mammals due to chronic toxicity observed in mammals;
assessment factor = 10.0
concern concentration = 0.050 mg/L (ppm)

PART V: RAD RISK RATIONALE: HUMAN HEALTH

PART VI: SUMMARY OF EXPOSURE/RELEASE

(50 ppb):

PART VII: FOCUS DECISION AND RATIONALE

DISPOSITION: LVE Denial

RATIONALE: L08-0037 was denied based on PBT concerns. The PBT rating for the degradation product was P2B1T3, but the B rating is uncertain. There were high human health concerns for reproductive and developmental effects, liver effects, immunotoxicity, and a marginal concern for oncogenicity based on analogy to PFOA . Ecotoxicity concerns for the parent and the deg product were based on analogue test data and analogy to PFOA. submitted ecotoxicity test data that will apply to this LVE.

PART VIII: CCD DISPOSITION / DD

CCD: